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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,027	06/29/2001	Olaf Isele	8610	7458

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EXAMINER	
CHANNAVAJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/895,027

Applicant(s)

ISELE ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Reply Brief dated 4-11-05 is acknowledged.

In view of the new argument presented by the examiner in the Examiner's Answer (2-9-05) and applicant's request for reconsideration of the finality of the rejection, the finality of that action is withdrawn.

The following rejection has been applied:

Claims 1-3 and 5-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64502 (hereafter WO).

Instant claims are directed to an article such as a diaper or a sponge, comprising a porous substrate having a contacting surface and an opposing surface, wherein the contacting surface is disposed with a s beneficial agent and a means for minimizing migration of the beneficial agent into the porous substrate, whereby the ratio of the amount of beneficial component present in the top third portion of the substrate is about 2.2 times the amount of the beneficial agent present in the bottom 2/3 portion of the substrate. Dependents claims further define beneficial agents, disposing the beneficial agent in layers and method of top-biasing a composition on a porous substrate.

Independent claim 9 recites a first layer of 5% to 95% of beneficial component on the contacting surface followed by a depositing a second layer. Independent claim 16 recites a method of top-biasing article by applying a first layer of relatively hydrophilic component followed by applying a relatively hydrophobic component allowing the first and second layers to cool without formation of an emulsion.

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WO teaches an absorbent article having a liquid impermeable outer surface, a middle absorbent portion and a top liquid permeable bodyside liner facing the wearer (see figure 2 of WO). WO teaches that the bodyside liner may be made of woven or nonwoven materials, less hydrophilic to be dry and porous (page 12, lines 15-32). The bodyside liner includes a lotion formulation on the outer bodyfacing surface and is comprised of wax, emollient and a viscosity enhancer that acts as a lubricant to reduce the abrasion of skin caused by liner. The emollient lubricates skin and upon transfer to the skin improved skin condition (abstract, page 13, lines 15-22) and includes fatty alcohols, lanolin or lanolin derivatives, petroleum based oils (page 13, lines 22-35). WO teaches waxes for immobilizing the emollient and reduce its tendency to migrate (page 14), viscosity enhancers such as talc, silica, cellulose and modified cellulose derivatives and other skin treating compounds such as glycerin, zinc oxide, etc (page 15 and 16).

WO does not teach the claimed thickness of the beneficial components on the porous substrate i.e., 2.2 times more in the top third portion of the porous substrate than the bottom 2/3 portions. However, WO teaches that the lotion can be applied to the bodyside liner at 0.05-100 mg/sq. cm. Accordingly, it would have been within the scope of a skilled artisan to optimize the amounts of lotion applied on the absorbent applied on the article. The expected result would be a minimum migration of the solidified components applied to the bodyside line. A careful review of the instant specification also reveals that the same end result i.e., minimizing the migration of lotion is achieved by the applicants by incorporating viscosity enhancing agents (page 18) and hydrophobic agents such as wax, both of which are taught by WO. Further, WO states

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that a z-direction migration loss test shows that the migration of the lotion on the absorbent article is very low. With respect to the claims 9 and 16, WO does not explicitly teach layers of beneficial component or disposing a first hydrophilic layer followed by a hydrophobic layer. However, WO suggests limiting the lotion to restricted areas of the article such that migration to the interior or lateral migration of the absorbent body is not observed. Further, WO teaches applying the lotions to discreet areas as stripes as full length or a portion of the article and further in an add-on level, including the claimed steps of applying the component and solidifying (page 19). WO also teaches deposition of wax, emollients and other viscosity enhancers such as celluloses, silica, petrolatum, aloe etc., all of which read on instant hydrophilic components, along with emollients and wax (hydrophobic) in the lotion formulation. WO suggests that the lotion formulation be applied to the entire body face or may be applied selectively to particular sections, so as to provide greater lubricity to such sections and can be applied in stripes (page 18, lines 26-33) and suggests that the lotion formulation leave a greater percentage of the added formulation on the bodyfacing surface of the liner where it can contact and transfer to the wearer's skin to provide a benefit (page 3, lines 1-7). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to apply the lotion composition in a desired thickness or amounts so as to add a greater amount of the lotion on the body facing portion of the liner, with an expectation to exhibit minimum migration because WO suggests that the wax and viscosity enhancer containing lotion solidifies at the site of deposition due to the high melting agents and therefore do not migrate from their position (paragraph bridging pages 2-3).

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Further, adding the beneficial agents, hydrophobic or hydrophilic or both, in discreet patterns such as layers or stripes etc., and allowing the component to result in a proper composition, such emulsion formation or suspension or solution without affecting the optimum migration of the beneficial components would have been within the scope of a skilled artisan.

Response to Arguments

Applicant's arguments filed 4-11-05 have been fully considered but they are not persuasive.

Applicants state that the office fails to present a factual support or a convincing line of reasoning in support of a reasonable expectation of success for the Office's proposed modification (page 2 1st full paragraph of Reply Brief). Applicants argue that the office relies on the teaching of Krzysik teaches that "the articles having the lotion formulation of the present invention applied there to bodyside liner define a z-direction migration loss of no more than about 55%", to support the notion that the amount of lotion applied to the liner (i.e., 0.05-100 mg/cm²) results in the recited Z-directed migration loss. It is argued that Krzysik teaches the z-direction migration loss of lotion formulation and that office pointed nothing to suggest that the amount of lotion applied on the article. Applicants also argue that there is no support for the office's assertion that "it would have been within the scope of a skilled artisan to optimize the amount of lotion applied on the article".

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Applicants arguments are not persuasive because Krzysik defines z-direction migration loss as the value obtained when subjecting an absorbent article having a lotion formulation on the bodyfacing surface thereof to the Z-direction migration test (page 3, last paragraph); and the said Test itself measures the quantity of lotion that remains as compared to the amount of lotion migrated (see description of Z-direction migration test on page 21, lines 4-16). Further, Krzysik states that the amount of the lotion formulation can be reduced and still obtain the benefit of localizing the lotion on the bodyside of the liner (page 5, lines 14-18). This is further emphasized by the teachings of Krzysik on page 14, lines 31 through page 15, lines 9, which clearly reeferes to the ability of lotion to remain in place and not migrate. Thus, it is clear that the lotion migration of Krzysik is in fact measuring the migration of the amount of the lotion and the assertion made by the office is completely supported by the teachings of Krzysik.

Applicants argue that the office reliance of Z-direction lotion migration test of Krzysik is misplaced and a skilled artisan would recognize the limitations of the said test because the test cannot determine lotion presence in the sample as a whole and cannot determine if lotion migration is due to migration in the z-direction alone. It is argued that one skilled in the art would not read as much breadth in the z-direction lotion migration loss as does the office because the example of Kryzysik teaches migration loss of 44.3% and a skilled artisan would not read any further migration loss from disclosure absent undue experimentation and excessive experimentation. Applicants arguments are not persuasive because Krzysik teaches the amount of lotion migration desired, the direction of loss that is undesirable in terms of the reduced abrasion to skin and also the

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migration of the lotion as a function of the viscosity of the lotion (page 17, lines 30-35), thus providing enough guidance to one skilled in the art to determine the amount of lotion present on the bodyside liner as compared to the amount migrated, without any undue experimentation. Further, Krzysik teaches that the minimum migration of the lotion formulation is no more than 55% (page 17), where it is clearly suggested that preferably the migration loss is no more than 55%, preferably no greater than 40%, more desirably no more than 35%, suggesting the amount of migration permitted and thus enabling one skilled in the art to choose a lotion formulation of desired viscosity and migration loss.

Applicants argue that the reference relied fails to teach a beneficial component comprising at least a first layer and a second layer. Instant claim 1 only states first and second layer, but does not require that the two layers be different and this. This assumption is further supported by claim 5, which requires both layers to be distinct. In other words, it is only in claim 5 and not claim 1 that both layers need to be different. Moreover, instant specification states (page 16) that the hydrophilicity and hydrophobicity of the first and second layers is not critical. Further, applicants have not shown any unexpected results with the beneficial component being in the form of layers as opposed to being applied as a single composition. Accordingly, incorporating the beneficial component on the article as a single (layer) component or as different layers by routine optimization would be within the gambit of a skilled artisan. Applicants' argument that Krzysik does not support incorporating beneficial component in the form of layers is incorrect because on page 13, starting at line 2, Krzysik teaches treating the

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surface of the article with a surface-active agent (constituting first beneficial layer), followed by lotion formulation (second beneficial agent). Thus Krzysik does teach adding two layers of beneficial components.

With respect to the unexpected results described on page 23 of the specification, applicants argue that glycerin has been listed as a conditioning agent and hence reads on a beneficial agent. Applicants argue that the unexpected results have support. However, applicants' arguments are not persuasive because while the results are specific to glycerin, instant claims are not limited to glycerin alone and the unexpected results cannot be extrapolated to the numerous beneficial agents that are within the scope of the instant claims. Krzysik teaches emollients and viscosity enhancers, the latter group comprising polymers such as cellulose, and accordingly, choosing the desired beneficial component and in optimum concentrations in the article of Krzysik, so as achieve the desired benefit of providing the emollients or lubricants to the skin of the wearer would have been within the scope of a skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

June 16, 2005



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